

K061170

Appendix D: 510(k) Submission for Pediatric Head/Spine

510(k) Summary

1. Manufacturer Name & Address: Resonance Innovations LLC
12530 Harney Circle
Omaha, NE 68154
Establishment Registration No.: 1932898
Applicant/Contact Person: Randall Jones, Dr.Eng.
Applicant Contact Info : Phone: 402-934-2650
Fax: 402-778-9699
Email: info@scanmed.com
Date Prepared: April 22, 2006
MAY 25 2006
2. Device common name: MRI Accessory Coil
Specific Device Trade Name: 3.0T Pediatric Head and Spine Array
Classification: Class II/Radiology/LNH
3. Unmodified Device Trade Name: 1.5T Pediatric Array #801GE1500
Unmodified Device 510(k) No.: k951649.
4. Device Description: The 3.0T Pediatric Head and Spine Array, Catalog #808GE3000, interfaces with the G.E. 3.0 Tesla Excite® system. It has been designed and optimized to collect spine (cervical, thoracic, and lumbar) and brain image data from many overlapping coil groups. The multi-channel design utilizes the G.E. Phased Array Coil inputs and utilizes standard coil configuration files available on the G.E. system. The coil form geometry has been formed to facilitate close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest. The coil assembly comes with a comfort pad set to comfortably place the patient on the coil assembly.
5. Intended Use Statement:
 - i. Soft tissue and bone imaging of the spine and brain as allowed by the MRI system.
 - ii. Magnetic resonance angiography.

Note that the intended use is not substantively different than that of the unmodified device (below).

 - i. Soft tissue and bone imaging of the spine and brain as allowed by the MRI system.
 - ii. Magnetic resonance angiography.
6. The modified device has the same technological characteristics as the unmodified device with only minor changes to the size and physical orientation of the individual elements of the multi-element or multi-channel MRI antenna (coil). The materials, use, and safety features are equivalent. Both are receive-only MRI antennas so no energy is imparted to the patient.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 25 2006

Randall W. Jones, Dr. Eng.
President
Resonance Innovations LLC
12530 Harney Circle
OMAHA NE 68154

Re: K061170

Trade/Device Name: 3.0T Pediatric Head and Spine Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: April 22, 2006
Received: April 27, 2006

Dear Dr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix A: 510(k) Submission for Pediatric Head/Spine**Statement of Indications for Use**

The new device labeled the 3.0T Pediatric Head and Spine Array will have no substantive change in the Indications for Use over the predicate (unmodified) device, 1.5T Pediatric Array (k951649).

The intention of the new device is to expand the anatomical coverage provided by the device by modifying the patient-user interface in terms of altering the size and anatomical location of some of the array's individual resonators, as well as adding resonators. The new device also adds parallel imaging compatibility.

The Intended Use Statements remain virtually identical to those of the unmodified device. These statements follow.

- i. Soft tissue and bone imaging of the spine and brain as allowed by the MRI system.
- ii. Magnetic resonance angiography.

Prescription Use ✓

Nancy C. Brydon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061170